OIPE JC26
APR 26 2004
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Laura S.L. GAETA *et al.*

Application No. 10/649,138

Filed: August 26, 2003

For: **Novel Amylin Agonist Peptides and Uses Therefor (as amended)**

Group Art Unit: 1646

Examiner: To Be Assigned

Atty. Docket: 248/182 CON / 18528.641

Confirmation No.: 8797

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the references listed on the attached Form PTO-1449. These references were previously considered in earlier filed U.S. Patent Application Serial No. 09/454,533, filed December 6, 1999, now US Patent 6,610,824, which is a continuation of Application No. 08/892,549, filed July 14, 1997, now US Patent No. 5,998,367, which is a divisional of Application No. 08/447,849, filed May 23, 1995, now US Patent No. 5,686,411, which is a continuation of Application No. 07/794,266, filed November 19, 1991, now abandoned, which is a continuation-in-part of Application No. 07/667,040, filed March 8, 1991, upon which the instant application relies on for an earlier effective filing date under 35 U.S.C. 120. Applicants further submit that the references filed in the Information Disclosure Statement in the earlier applications complied with 37 C.F.R. 1.98(a)-(c). Accordingly, Applicants submit that under 37 C.F.R. 1.98(d)(1)-(2), copies of the listed references need not be provided. However, the Examiner is requested to notify the Applicants should he/she require a copy of any or all of the listed references.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,

Milan M Vinnola

David R. Marsh (Reg. No. 41,408)
Milan M. Vinnola (Reg. No. 45,979)

Date: April 26, 2004

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OIPE JC46 APR 26 2004 PATENT & TRADEMARK OFFICE

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.	APPLICATION NO.
18528.641	10/649,138
APPLICANTS	
Laura S.L. GAETA *et al.*	
FILING DATE	GROUP
August 26, 2003	1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,743,677	5/1988	NODA *et al.*			
	AB1	4,992,530	2/1991	MORITA *et al.*			
	AC1	5,112,945	5/1992	WESTERMARK *et al.*			
	AD1	5,116,948	5/1992	WESTERMARK *et al.*			
	AE1	5,124,314	6/1992	COOPER			
	AF1	5,175,145	12/1992	COOPER			
	AG1	5,234,906	8/1993	YOUNG *et al.*			
	AH1	5,266,561	11/1993	COOPER *et al.*			
	AI1	5,281,581	1/1994	COOPER *et al.*			
	AJ1	5,298,605	3/1994	WESTERMARK *et al.*			
	AK1	5,321,008	6/1994	BEAUMONT *et al.*			
	AL1	5,367,052	11/1994	COOPER *et al.*			
	AM1	5,405,831	4/1995	MACINTYRE *et al.*			
	AN1	5,424,221	6/1995	WESTERMARK *et al.*			
	AO1	5,424,394	6/1995	LEHMAN DE GAETA *et al.*			
	AP1	5,508,260	4/1996	BEAUMONT *et al.*			
	AQ1	5,527,771	6/1996	BEAUMONT *et al.*			
	AR1	5,641,744	6/1997	COOPER *et al.*			
	AS1	5,656,590	8/1997	RINK *et al.*			
	AT1	5,686,411	11/1997	GAETA *et al.*			
	AU1	5,998,367	12/1999	GAETY *et al.*			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AF1	0 309 100	3/1989	Europe			X Yes No
	AG1	0 408 294	7/1990	Europe			X Yes No

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

* Copies of the listed references were previously cited by or submitted to, the Office in a prior application. Pursuant to 37 C.F.R. §1.97(d) and MPEP §609, the indicated reference may have been previously cited by or submitted to, the Office in a prior application, where the prior application is identified by its U.S. Application Number in this Information Disclosure Statement.

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	FILING DATE August 26, 2003	GROUP 1646

FOREIGN PATENT DOCUMENTS

	AA2	WO 89/06135	7/1989	PCT			Yes No
	AB2	WO 90/06936	61990	PCT			Yes No
	AC2	WO 92/11862	7/1992	PCT			Yes No
	AD2	WO 92/11863	7/1992	PCT			Yes No
	AE2	WO 92/15317	9/1992	PCT			Yes No
	AF2	WO 93/10146	5/1993	PCT			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AG2	Bell, "Molecular Defects in Diabetes-Mellitus", Diabetes, 40:413-422 (1991).
	AH2	Betsholtz *et al.*, "Islet Amyloid Polypeptide (IAPP): cDNA Cloning and Identification of an Amyloidogenic Region Associated with the Species-Specific Occurrence of Age-Related Diabetes Mellitus", Experimental Cell Research, 183:484-493 (1989).
	AI2	Betsholtz *et al.*, "Sequence divergence in a specific region of islet amyloid polypeptide (IAPP) explains differences in islet amyloid formation between species", FEBS Letters, 251:261-264 (1989).
	AJ2	Clark *et al.*, "Islet Amyloid Formed From Diabetes-Associated Peptide May be Pathogenic in Type-2 Diabetes", The Lancet, 2(8553):231-234 (1987).
	AK2	Cooper *et al.*, "Amylin and the amylin gene: structure, function, and relationship to islet amyloid and to diabetes mellitus", Biochem. Biophys. Acta., 1014:247-258 (1989).
	AL2	Cooper *et al.*, "The Amylin Superfamily: A Novel Grouping of Biologically Active Polypeptides Related to the Insulin A-Chain", Prog. Growth Factor Research, 1:99-105 (1989).
	AM2	Cooper *et al.*, "Purification and characterization of a peptide from amyloid-rich pancreases of type 2 diabetic patients", Proc. Natl. Acad. Sci., 84:8628-8632 (1987).
	AN2	Cooper *et al.*, "Amylin Found In Amyloid Deposits In Human Type 2 Diabetes Mellitus May Be A Hormone That Regulates Glycogen Metabolism In Skeletal Muscle", Proc. Natl. Acad. Sci., 85:7763-7766 (1988).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)		
	AA3	Cooper *et al.*, "Amylin and Non-Insulin-Dependent (Type 2) Diabetes Mellitus", Diabetes 1988, ed. Larkins, R., Zimmet, P. & Chisholm, D. (Elsevier, Amsterdam), pp 493-496 (1989).
	AB3	Dayoff *et al.*, "A Model of evolutionary Change in Proteins", Atlas of Protein Sequences & Structure, Vol. 5, pp 89-99 (1972).
	AC3	Deems *et al.*, "Amylin of CGRP (8-37) Fragments Reverse Amylin-induced Inhibition of ^{14}C-Glycogen Accumulation", Biochem. Biophys. Res. Commun., 181(1):116-120 (1991).
	AD3	Doherty, "Endogenous Vasoactive Peptides", Annual Reports in Medicinal Chemistry, 26:83-92 (1991).
	AE3	Fujii *et al.*, "Synthesis of Second Human Calcitonin Gene-Related Peptide (β-hCGRP) by Application of a New Disulfide-Bonding Reaction with Thallium(III) Trifuoroacetate", Chem. Pharm. Bull., 35(12):4769-4776 (1987).
	AF3	Fujii *et al.*, "Syntheses of Cystine-Peptides by Oxidation of S-Protected Cysteine-Peptides with Thallium(III) Trifuoroacetate", Chem. Pharm. Bull., 35(6):2339-2347 (1987).
	AG3	Glenner *et al.*, "Amyloid Fibrils Formed from a Segment of the Pancreatic Islet Amyloid Protein", Biochem. Biophys. Res. Commun., 155(2):608-612 (1988).
	AH3	Goodman and Gilman's "The Pharmacological Basis of Therapeutics", Chapter 38 Pergamon Press, Eighth Edition (1990).
	AI3	Gustavsson *et al.*, "Normal Transthyretin and Synthetic Transthyretin-Fragments form Amyloid-Like Fibrils in Vitro", Biochem. Biophys. Res. Commun., 175(3):1159-1164 (1991).
	AJ3	Hilbich *et al.*, "Aggregation and Secondary Structure of Synthetic Amyloid .beta.A4 Peptides of Alzheimer's Disease", J. Mol. Biol., 218:149-163 (1991).
	AK3	Hiskey *et al.*, "Sulfhydryl Group Protection in Peptide Synthesis", The Peptides, Vol. 3, Chapter 3, pp 137-167 (1981).
	AL3	Hubbard *et al.*, "Solution structures of calcitonin-gene-related-peptide analogues of calcitonin-gene-related-peptide and amylin", Biochem. J., 275:785-788 (1991).

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		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AA4	Johnson *et al.*, "Islet Amyloid Polypeptide: Mechanisms of Amyloidogenesis in the Pancreatic Islets and Potential Roles in Diabetes Mellitus", Laboratory Investigation, 66(5):522-535 (1992).
	AB4	Johnson *et al.*, "Factors Affecting Diabetogenesis and Amyloidogenesis are Provided by Studies of IAPP in the Dog and Cat", In Natvig, J.B. et al., Editors, Amyloid and Amyloidogenesis, 1990. Norwall, Mass, Kluwer Academic Publishers, pp. 445-448 (1991).
	AC4	Johnson *et al.*, "Islet Amyoid, Islet-Amyloid Polypeptide, and Diabetes Mellitus", New England Journal of Medicine, 321(8):513-518 (1989).
	AD4	Johnson *et al.*, "Newly Identified Pancreatic Protein Islet Amyloid Polypeptide", Diabetes, 40:310-314 (1991).
	AE4	Johnson *et al.*, "Amyloid in the Pancreatic Islets of the Cougar (Felis Concolor) is derived from Islet Amyloid Polypeptide (IAPP)", Comp. Biochem. Physiol., 98B(1):115-119 (1991).
	AF4	Jordan *et al.*, "Canine IAPP cDNA Sequence Provides Important Clues Regarding Diabetogenesis and Amyloidogenesis in Type 2 Diabetes", Biochemical and Biophysical Research Communications, 169(2):502-508 (1990).
	AG4	Leffert *et al.*, "Rat amylin: Cloning and tissue-specific expression in pancreatic islets", Proc. Natl. Acad. Sci. (PNAS), 86:3127-3130 (1989).
	AH4	Leighton *et al.*, "Pancreatic amylin and calcitonin gene-related peptide cause resistance to insulin in skeletal muscle in vitro", Nature, 335(6191):632-635 (1988).
	AI4	Leighton *et al.*, "Amylin inhibits glucose utilization in the soleus muscle of the rat in vitro", Diabetologia, 31:513 A [Abstract 288] (1988).
	AJ4	Nishi *et al.*, "Conservation of the sequence of islet amyloid polypeptide in five mammals is consistent with its putative role as an islet hormone", Proc. Natl. Acad. Sci., 86:5738-5742 (1989).
	AK4	O'Brien *et al.*, "Islet Amyloid Polypeptide and Insulin Secretion from Isolated Perfused Pancreas of Fed, Fasted, Glucose-Treated, and Dexamethasone-Treated Rats", Diabetes, 40:1701-1706 (1991).
	AL4	Ohagi *et al.*, "Sequences of islet amyloid polypeptide precursors of an old world monkey, the pig-tailed macaque (*Macaca nemestrina*), and the dog (*Canis familiaris*)", Diabetologia, 34:555-558 (1991).

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		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AA5	Pettersson *et al.*, "Calcitonin Gene-related Peptide: Occurrence in Pancreatic Islets in the Mouse and the Rat and Inhibition of Insulin Secretion in the Mouse", Endocrinology, 119(2):865-869 (1986).
	AB5	Porte *et al.*, "β-Cells in Type II Diabetes Mellitus", Diabetes, 40:166-180 (1991).
	AC5	Poyner, "Pharmacology of receptors for calcitonin gene-related peptide and amylin", TiPS, 16(12):424-428 (1995).
	AD5	Roberts *et al.*, "Molecular and functional characterization of amylin, a peptide associated with type 2 diabetes mellitus", Proc. Natl. Acad. Sci. (PNAS), 86:9662-9666 (1989).
	AE5	Saldanha *et al.*, "Molecular model-building of amylin and α-calcitonin gene-related polypeptide hormones using a combination of knowledge sources", Protein Engineering, 4(5):539-544 (1991).
	AF5	Stridsberg *et al.*, "Islet Amyloid Polypeptide (IAPP)", Acta Oncologica, 30(4):451-456 (1991).
	AG5	Westermark *et al.*, "A Novel Peptide in the Calcitonin Gene Related Peptide Family as an Amyloid Fibril Protein in the Endocrine Pancreas", Biochemical and Biophysical Research Communications, 140(3):827-831 (1986).
	AH5	Westermark *et al.*, "Islet Amyloid in Type 2 Human Diabetes Mellitus and Adult Diabetic Cats Contains a Novel Putative Polypeptide Hormone", Am. J. Pathology., 127(3):414-417 (1987).
	AI5	Westermark *et al.*, "Islet Amyloid Polypeptide: Pinpointing Amino Acid Residues Linked to Amyloid Fibril Formation", Proc. Natl. Acad. Sci., 87:5036-5040 (1990).
	AJ5	Westermark *et al.*, "Islet amyloid polypeptide (IAPP) and pro-IAPP immunoreactivity in human islets of Langerhans", Diabetes Research and Clinical Practice, 7:219-226 (1989).
	AK5	Westermark, "Islet amyloid polypeptide in humans and cats", in Frontiers in diabetes research. Lessons from animal diabetes III, Shafrir, E., Eds., X.2:498-501, Smith-Gordon (1990).
	AL5	

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